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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,946	08/22/2001	Charles Chauveau	C1190/20008	5350

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,946	CHAUVEAU ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination, and Extension of Time received on April 16, 2004 is acknowledged. Claims **48-74** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation of "said active principle not being intimately dispersed or dissolved in a pharmaceutically acceptable lipid" does not have support in the specification. If this is not new matter, applicant is requested to clearly point support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The parent claims 48 and 61 recite a lubricant as a required component in the formulation. Therefore, the recitation of "wherein the mixture of excipients further comprises lubricants..." in claims 49 and 62 is unclear since it is not clear what the applicant is further

limiting. Further, it is unclear if the recitation "lubricants, sweeteners, flavorings and colors" is part of a Markush group or if all elements are required. Further clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (6,465,009) in view of Ku et al (5,994,348).

Liu et al teach a rapidly disintegrating tablet in about 1 to 40 seconds (col. 2, lines 45-51). Liu teaches a formulation containing a coated active such as ibuprofen and acetaminophen (up to 50%; exemplified 8.7%), a binder (0.5-5%), at least one lubricant such as magnesium stearate (0.5-1%), and fillers (mannitol, xylitol) (40-99%). See column 3, lines 5-15, column 7, lines 5-20, and examples. Liu et al teach croscarmellose sodium as an additional disintegrant. See column 7, lines 64-68. Sweetening agents such as aspartame are taught on column 8.Liu teaches

lubricants help in manufacturing of the tablet such as helping prevent the ejection sticking of the compressed formulation to the pressing dies and sticking. See column 7, lines 60-64.

Liu et al does not teach inclusion of a permeabilizing agent.

Ku et al teach a pharmaceutical composition with excellent wetting, disintegration, and rapid release properties (col. 2, lines 5-15). Ku teaches the use of anti-adherents such as .25-5% silicon dioxide reduce the stickiness of the formulation and prevent adherence to metal surfaces. (col. 4, lines 20-30). Further, Ku teaches the combination of magnesium stearate and silicon dioxide provides a superior lubrication effect while minimizing any decline in tablet dissolution performance (col. 5, lines 59-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Liu et al and Ku et al and to look to Ku et al and include silicon dioxide in the composition. One would be motivated to do so since Ku teaches the advantages of using an anti-adherent agent in reducing the stickiness of the composition and Lu teaches the problem of "ejection sticking". Further, one would expect similar results since Ku teaches the combination of magnesium stearate, a lubricant utilized by Liu, and silicon dioxide provide for an excellent lubricating effect.

Response to Arguments

Applicant argues that there is no motivation to combine Liu et al and Ku et al and utilize the instant permeabilizing agent. Applicant argues that croscarmellose is not specifically mentioned in Liu et al. Applicant argues that Liu et al solve the problem of "sticking" by utilizing magnesium stearate and thus there is not motivation to look outside of Liu et al.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to column 7, line 67 wherein Liu et al clearly discloses the use of croscarmellose as a disintegrant to further enhance the rate of disintegration. It is acknowledged that Liu teaches that lubricants help in manufacturing of the tablet and help prevent the ejection sticking of the compressed formulation to the pressing dies and sticking. However, Ku teaches the combination of silicon dioxide and magnesium stearate has a superior lubricating effect while minimizing any decline in tablet dissolution. See column 5, lines 59-64. Therefore, it is clear that Ku teaches an improved combination of magnesium stearate and silicon dioxide for overcoming the sticking problem without giving up dissolution of the tablet. Thus, there is clearly a motivation to look to Ku et al to yield an improved dosage form that is manufactured easily without jeopardizing the dissolution rate of the tablet.

Claims 48-74 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Augello et al (6,099,865) in view of in view of Myers et al (5,567,439).

Augello et al teach a rapid disintegrating composition containing a croscarmellose coated active particles. The croscarmellose coating material is utilized in the range of 10-50 percent and has a dual purpose of making the active and acting as a super disintegrant. See column 2, lines 41-65. When the croscarmellose is incorporated into the final composition, it is used in the amount of 1-10%. See column 4, lines 48-52. The actives that are suitable include acetaminophen and ibuprofen. See column 4, line 25. Sweeteners such as aspartame and granular mannitol in instant amounts (46%) are taught. See examples. The composition includes 0.82% magnesium stearate. Disintegration rates of 30 and 50 seconds are taught in the examples.

Augello et al do not teach the permeabilizing agent.

Meyers et al teach glidants such as silica compounds such as SYLOID in the amount of 0.50% are useful in tabletting since they enhance flow properties by reducing interparticle friction. Furthermore, isoamorphous silicate is used as a disintegrant to enhance the dispersibility of compressed tablets in aqueous environments. See column 13, lines 55-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Augello et al and Meyers et al and utilize silica for its dual purpose. One would be motivated to do so since Meyers teaches silica compound are not only useful as disintegrants but also as glidants in the tabletting process. Therefore, one would be motivated to add silica to increase the rate of disintegration since adding silica would have an obvious additive effect with the disintegrant croscarmellose since both have the same function in the composition. Additional motivation is to enhance flow properties and reduce interparticle friction when tabletting the formulation.

Response to Arguments

Applicant's arguments pertaining to Augello et al are confusing. Applicant argues that Augello et al teaches the use of croscarmellose as a coating agent and as a disintegrant; therefore there is not motivation to utilize silica. It is further argued that the instant invention does not utilize croscarmellose as a coating agent.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that it is quite conventional in the art to utilize combination of disintegrants for the purpose of an additive effect for faster dissolution. Secondly, it is pointed out that the Augello et al teach the use of conventional additives in the composition such as flow aids. Meyers et al not only teaches the use of silica as a flow aid to reduce particles friction but

also as a disintegrant. Therefore, a skilled artisan would not only be motivated to use silica to provide for easier manufacturing of the dosage form but also for its additive effect as a disintegrant to provide for a rapid dissolving dosage form. It is the examiner's position that the use of conventional additives such as silica or silicon dioxide is within the skill of a pharmaceutical artisan. Lastly, it is pointed out that the claims are directed to a product claim and the use of a certain component does not hold patentable unless denotes a structural limitation. Therefore, since the claims only require the presence of croscarmellose and clearly Augello et al teach croscarmellose, the claims are not distinguishable over the prior art.

Therefore, the rejection of all the claims is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48, 50-54, 61, 63,65, and 67-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 11-12 of U.S. Patent No. 6,106,861. Although the conflicting claims are not identical, they

are not patentably distinct from each other because the claimed subject matter in instant application and US patent '861 are obvious modifications of each other.

Instant application recites a multiparticulate tablet, which disintegrates in contact with the saliva in the mouth in less than 40 seconds, wherein it is based on:

A) particles of coated active principle, and

B) mixture of excipients being free of effervescent agents and the ratio of excipient mixture to coated active principle particles being 0.4 to 6 parts by weight, the mixture of excipients comprising: a disintegration agent; a soluble diluent with binding properties which is a polyol with less than 13 carbon atoms, with an average particle diameter of 100 to 500 um, a lubricant, a permeablizing agent, the proportion of disintegration agent being 1 to 15% by weight and the proportion of soluble agent being 30 to 90% by weight, based in each case on the weight of the tablet.

Dependent claims recite the Markush group xylitol, sorbitol, and maltitol as the soluble diluent. Dependent claims recite aspirin, ibuprofen, and paracetamol.

US patent claims a multiparticulate tablet, which disintegrates in the mouth in less than 40 seconds, wherein it is based on:

A) particles of coated active principle and

B) mixture of excipients of 3-15% of a disintegrant selected from crosslinked PVP or crosslinked sodium carboxymethylcellulose, and 40-90% soluble diluent with binding properties which is a polyol with less than 13 carbon atoms selected from mannitol xylitol, sorbitol, and maltitol. Dependent claims recite aspirin, ibuprofen, ketoprofen, loperamide, and paracetamol.

The instant application and US '861 contain overlapping subject matter as set forth above and thus are rejected under obviousness double patenting.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:00), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER